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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,131	09/20/2005	Karen McLachlan	2159.0640004/EKS/PAC/DLL	6721

53644 7590 10/14/2008  
STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.  
1100 NEW YORK AVE., N.W.  
WASHINGTON, DC 20005

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/509,131

**Applicant(s)**

MCLACHLAN ET AL.

**Examiner**

Alana M. Harris, Ph.D.

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09/05/2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.  
4a) Of the above claim(s) 1-3 and 7-42 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 4-6 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/CIS)  
Paper No(s)/Mail Date 04/12/2008  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group III (claims 4-6, with the further election of SEQ ID NO: 21) in the reply filed on September 5, 2008 is acknowledged.

2. Claims 1-42 are pending.

Claims 1-3 and 7-42, drawn to non-elected inventions are withdrawn from examination.

Claims 4-6 are examined on the merits, to the extent the nucleic acid sequence is SEQ ID NO: 24.

***Claim Objections***

3. Claim 4 is objected to because of the following informality: it references non-elected sequences. Correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,623,923 (filed September 22, 1999). Applicants' claim language includes the language, "...a *nucleotide sequence* of ...SEQ ID [NO]: 24...". The claim does not require "the nucleotide sequence of SEQ ID NO: 24" or "the full length sequence of SEQ ID NO: 24", hence the following prior art reads on the claims.

The patent teaches a method of diagnosing colon cancer comprising detecting sequence 1706, which shares sequence identity with Applicants' SEQ ID NO: 24, see sequence alignment. The disclosed method comprises detecting SEQ ID NO: 24 using a nucleic acid that specifically hybridizes to a nucleotide sequence of SEQ ID NO: 24 using microarray analysis, as well as obtaining a biological sample, see the abstract; column 36, lines 29-55; and column 43, lines 28-50. "Polynucleotide primers and probes may be used to detect the level of mRNA encoding a tumor protein, which also indicative of the presence or absence of cancer.", see column 36, lines 40-43. The said primers can be used in methods of detection implementing amplification, see column 39, line 64-column 40, line 47.

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RESULT 4
US-09-401-064-131/c
; Sequence 131, Application US/09401064
; Patent No. 6623923
; GENERAL INFORMATION:
; APPLICANT: Xu, Jiangchun
; APPLICANT: Lodes, Michael J.
; APPLICANT: Secrist, Heather
; APPLICANT: Benson, Darin R.
; APPLICANT: Meagher, Madeline Joy
; APPLICANT: Stolk, John A.
; APPLICANT: Wang, Tongtong
; TITLE OF INVENTION: COMPOUNDS FOR IMMUNOTHERAPY AND
; TITLE OF INVENTION: DIAGNOSIS OF COLON CANCER AND METHODS FOR THEIR USE
; FILE REFERENCE: 210121.471C2
; CURRENT APPLICATION NUMBER: US/09/401,064
; CURRENT FILING DATE: 1999-09-22
; NUMBER OF SEQ ID NOS: 371
; SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 131
; LENGTH: 554
; TYPE: DNA
; ORGANISM: Homo sapien
; FEATURE:
; NAME/KEY: misc_feature
; LOCATION: (1)...(554)
; OTHER INFORMATION: n = A,T,C or G
US-09-401-064-131

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Query Match		14.6%	Score 552.2;	DB 3;	Length 554;
Best Local Similarity		99.5%;	Pred. No. 2.4e-137;		
Matches 551;		Conservative	2;	Mismatches 1;	Indels 0; Gaps 0;
Qy	2771	CTGCTGCTGTGGCGTGTGTGGGCTGATCCCTTGAAGGCTGAGTTTTTGAGGGCAGAAA	2830		
Db	554	CTGCTGCTGTGGCGTGTGTGGGCTGATCCCTTGAAGGCTGAGTTTTTGAGGGCAGAAA	495		
Qy	2831	GCTAGCTATGGTAGCCAGGTGTACAAAGGTGCTGCTCCTTCTCCAAACCCCTACTTGGT	2890		
Db	494	GCTAGCTATGGTAGCCAGGTGTACAAAGGTGCTGCTCCTTCTCCAAACCCCTACTTGGT	435		
Qy	2891	TTCCCTCAACCCCAAGCCTCATTTGCTATACCAGCCAGTGGGTTCCAGAGAAGCATGACAC	2950		
Db	434	TTCCCTCAACCCCAAGCCTCATTTGCTATACCAGCCAGTGGGTTCCAGAGAAGCATGACAC	375		
Qy	2951	CTTATCACTCCCTCCTCTTGGGTGAGCTCTGAACACCAGCTTTTGGCCCTTCCACGTAAGG	3010		
Db	374	CTTATCACTCCCTCCTCTTGGGTGAGCTCTGAACACCAGCTTTTGGCCCTTCCACGTAAGG	315		
Qy	3011	CTGCTACATCAGGGGCAACCCGTGGCTCTATCATTTTCCCTTTTTTGCCAAAGGACCAGTA	3070		
Db	314	CTGCTACATCAGGGGCAACCCGTGGCTCTATCATTTTCCCTTTTTTGCCAAAGGACCAGTA	255		
Qy	3071	GCATAGGTGAGCCCTGAGCAGCTAAAGGAGGGGGTCCCTGAAGCTTTCCCACTATAGTGTG	3130		
Db	254	GCATAGGTGAGCCCTGAGCAGCTAAAGGAGGGGGTCCCTGAAGCTTTCCCACTATAGTGTG	195		
Qy	3131	GAGTTCTGTCCCTGAGGTGGGTACAGAGCCTTGGTTCCCTCTGGGGGTTGAGATAAGAA	3190		
Db	194	GAGTTCTGTCCCTGAGGTGGGTACAGAGCCTTGGTTCCCTCTGGGGGTTGAGATAAGAA	133		

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Qy      3191 TAGTGGGGAGGGAAAACTCCTCCTTGAAGATTTCCTGTCTCAGAGTCCCAGAGAGGTAG 3250
      |||
Db      134 TAGTGGGGAGGGAAAACTCCTCCTTGAAGATTTCCTGTCTCAGAGTCCCAGAGAGGTAG 75

Qy      3251 AAAGGAGGCAATTTCTCCTGGACTTTTATCTGGGCAGAGGAAGGATCGAATGAAGGTAGAAAA 3310
      |||
Db      74 AAAGGAGGCAATTTCTCCTGGACTTTTATCTGGGCAGAGGAAGGATCGAATGAAGGTAGAAAA 15

Qy      3311 AGGCAGAAATTACAG 3324
      |||
Db      14 AGGCAGAAATTACAG 1
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6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/509,131  
Art Unit: 1643

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Alana M. Harris, Ph.D.  
October 1, 2008  
/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643